IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

PACIRA BIOSCIENCES, INC., *Plaintiff,* v. NEPHRON PHARMACEUTICALS CORPORATION, *Defendant.*	)	C/A NO. 3:23-cv-05552-MGL **COMPLAINT** **(Jury Trial Demanded)**

Plaintiff Pacira BioSciences, Inc. ("Pacira"), brings this Complaint against Defendant Nephron Pharmaceuticals Corporation ("Nephron") and alleges as follows:

INTRODUCTION

1. This is a deeply troubling case in which Nephron, inflating its profits while potentially putting patients in grave danger, is claiming that its drug cocktail products are safe, effective, and approved by the Food and Drug Administration ("FDA") (when they are none of those things), by falsely advertising, literally or impliedly, that its products are generic to or substitutable for, if not superior to, a category-leading pain drug product from Pacira.

2. In a world where patients and providers are desperate for pain relief alternatives to highly-addictive opioids, Nephron has engaged in a sustained campaign to promote its drug cocktail products as safe and effective opioid alternatives through demonstrably false and misleading advertisements – including blatantly false statements that its drugs are safer and more effective than EXPAREL®, a product from Pacira that is the first long-lasting non-opioid drug approved by the FDA to reduce post-surgical pain.

3. Pacira brings this suit to prevent Nephron from misleading consumers as it callously attempts to put profits over patient safety by falsely advertising and promoting drug cocktails that have never been approved by the FDA.

4. Accordingly, with this suit, Pacira aims to stop Nephron from continuing its unlawful and willful false advertising practices, which have directly harmed Pacira and, in turn, have potentially put unsuspecting patients in harm's way.

Pacira's FDA-Approved EXPAREL® Product

5. Pacira is a leading provider of non-opioid pain management solutions.

6. Among other products, Pacira markets and manufactures EXPAREL®, the first long-lasting non-opioid drug approved by the FDA to reduce post-surgical pain.

7. EXPAREL® is injected at the surgical site during surgery or shortly thereafter to manage and reduce post-surgical pain for several days – all without the use of dangerous and addictive opioids.

8. The active ingredient in EXPAREL® is bupivacaine. EXPAREL® features a proprietary multivesicular liposome (pMVL) technology, which encapsulates bupivacaine in a suspension of multivesicular liposomes.

9. As a result of the process to secure FDA approval, EXPAREL® has undergone rigorous testing, studies, and analysis to confirm its efficacy and safety by the government and scientific community.

10. Prior to Pacira's development of EXPAREL®, costing millions of dollars over multiple years and requiring clinical trials to establish the safety and efficacy of this novel drug product, the only options for patients to manage and reduce post-surgical pain for several days were catheter based "pain pumps" or dangerous opioids.

11. Pacira in EXPAREL® created an entirely new category of long acting parenteral analgesics, with a current indication from the FDA for single-dose infiltration in patients aged six (6) years and older to produce post-surgical local analgesia and in adults as an interscalene brachial plexus nerve block to produce post-surgical regional analgesia, that last longer than eight (8) hours (collectively, this new category of drugs is identified herein as the "Post-Surgical Non-Opioid Regional Analgesia Category").

12. EXPAREL® for over ten (10) years has been, by a significant margin, the leading product in the Post-Surgical Non-Opioid Regional Analgesia Category.

13. Pacira has spent substantial resources on its marketing efforts to educate the healthcare market (and broader public) on the benefits of the Post-Surgical Non-Opioid Regional Analgesia Category and, within this larger category, the use of EXPAREL® to treat post-operative pain.

14. Pacira's marketing and education efforts over the last decade have paid off.

15. The Post-Surgical Non-Opioid Regional Analgesia Category has grown significantly, as health care providers and consumers learn and understand the benefits of long-lasting non-opioid pain control. Indeed, within the Postsurgical Non-Opioid Regional Analgesia Category, EXPAREL® has to date been used to treat over *10 million patients* across the United States.

Nephron's False Advertising And Unfair Competition
In Connection With Its Sale Of Unapproved Compounded Drug Cocktails

16. Nephron operates a compounding pharmacy.

17. Nephron advertises, markets, offers for sale, and sells compounded drug products that are not approved by the FDA ("Unapproved Compounded Drug Cocktails").

18. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[1]

19. Unapproved Compounded Drug Cocktails do not go through the FDA's extensive new drug approval process "which means [the] FDA has not evaluated their safety, effectiveness, or quality prior to marketing."[2]

20. As noted by the FDA, "[d]rugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether."[3] As such, compounded drugs can present a significant risk to patients.

21. Furthermore, co-packaged drugs – such as the Unapproved Compounded Drug Cocktails – pose unique safety and efficacy concerns because, even if the substances have been approved individually, they may present unforeseen risks when used in combination with each other.[4]

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[1] *Human Drug Compounding*, U.S. Food & Drug Administration, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (last visited Nov. 1, 2023).

[2] *FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders*, U.S. Food & Drug Administration, https://www.fda.gov/drugs/human-drug-compounding/fda-warns-patients-and-health-care-providers-about-potential-risks-associated-compounded-ketamine (last visited Nov. 1, 2023).

[3] *Warning Letter: www.gorillahealing.com*, U.S. Food & Drug Admin. (Oct. 2, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/wwwgorillahealingcom-664245-10022023.

[4] *See, e.g.*, Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph, 80 Fed. Reg. 79776, 79780 (Dec. 23, 2015).

22. The FDA has further stated that compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs," and as such, the "unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks" because "compounded drugs are not FDA-approved," meaning the "FDA does not verify their safety, effectiveness or quality before they are marketed."[5]

23. Notwithstanding these warnings from the FDA, Nephron advertises, markets, and sells its Unapproved Compounded Drug Cocktails as comparable to, and replacements for, Pacira's FDA-approved EXPAREL® bupivacaine product.

24. Recognizing the high and increasing demand for non-opioid analgesics, Nephron has marketed, developed, and sold new drugs for post-surgical relief in the Post-Surgical Non-Opioid Regional Analgesia Category – but without seeking let alone obtaining any FDA approval or completing any testing for safety and efficacy.

25. To circumvent FDA approval requirements established under the Federal Food, Drug, and Cosmetic Act ("FDCA") and flood the market with its illegal drugs as fast as possible, Nephron purports to rely on a very narrow exemption to new drug approval requirements for drugs that are "compounded" by registered "outsourcing facilities." This carefully-circumscribed exemption is commonly referred to as the "503B exemption."

26. Under that exemption, a compounded drug may be manufactured and sold without FDA approval, but only if that drug is expressly identified on the FDA's drug shortage or clinical need lists.

[5] *Compounding and the FDA: Questions and Answers*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (last visited Nov. 1, 2023).

27. Among the Unapproved Compounded Drug Cocktails it manufactures, markets, and sells, Nephron manufactures, markets, and sells "BKK" in the Post-Surgical Non-Opioid Regional Analgesia Category, which consists of ketorolac, ketamine, and bupivacaine in a syringe for combined use.

28. Nephron also manufactures, markets, and sells "RKK," another Unapproved Compounded Drug Cocktail, in the Post-Surgical Non-Opioid Regional Analgesia Category, which is a compounded drug consisting of syringes of ketorolac, ketamine, and ropivacaine for combined use.

29. Nephron claims that BKK and RKK meet the 503B exemption.

30. While its drugs have not been approved by the FDA, Nephron has distributed misleading advertisements and marketing materials that were intended to and implied the FDA has approved them.

31. Nephron falsely advertises the BKK and RKK Unapproved Compounded Drug Cocktails by making statements that describe EXPAREL® and the benefits of the Post-Surgical Non-Opioid Regional Analgesia Category as established by and relying upon EXPAREL®, but are false or misleading as to the BKK and RKK products.

32. Nephron has made misleading statements in advertising and promotions that claim or imply that the BKK and RKK Unapproved Compounded Drug Cocktail products have been approved by the FDA and/ or have been subjected to clinical studies and trials.

33. Using these false and misleading advertisements, Nephron has knowingly induced healthcare providers to purchase the BKK and RKK products on the mistaken belief that they have been approved by the FDA and/ or otherwise comply with the FDCA.

34. Upon information and belief, had healthcare providers known that the BKK and RKK products neither received FDA approval nor complied with federal law, they would likely have never purchased and used them. Using unapproved drugs that have not been evaluated for efficacy and safety presents inherent – and needless – risks to patient health and safety.

35. Pacira has been directly harmed by Nephron's unlawful conduct in the form of lost business, market share, sales, revenue, and profits, among other serious and ongoing harms. Indeed, Nephron has used its false and misleading statements in advertisements and marketing materials – along with pricing its drugs well below EXPAREL® – unlawfully to compete against Pacira and harm its business in the Post-Surgical Non-Opioid Regional Analgesia Category.

PARTIES

36. Pacira is a pharmaceutical company incorporated under the laws of Delaware with its principal place of business in Tampa, Florida.

37. Nephron is incorporated under the laws of Florida with its principal place of business in West Columbia, South Carolina.

JURISDICTION AND VENUE

38. The Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because Pacira asserts claims against Nephron under the Lanham Act, 15 U.S.C. §§ 1051, *et seq.*

39. The Court has general personal jurisdiction over Nephron because its principal place of business is in South Carolina.

40. The Court also has specific personal jurisdiction over Nephron because Nephron conducted and performed acts that are the subject of this Complaint in South Carolina.

41. Venue is proper in this Court because a substantial part of the events or omissions giving rise to Pacira's claims under the Lanham Act occurred in this District and Nephron is located in this District. *See* 28 U.S.C. § 1391(b)(1)-(2).

FACTS COMMON TO ALL CAUSES OF ACTION

FDA Approval Of Drug Products

42. The FDA has regulatory approval over the process for approving any "new drugs" that are developed for human use and consumption. 21 U.S.C. §§ 355 & 393(b).

43. To obtain approval of a new drug, an applicant must satisfy extensive application requirements that require substantial investments of capital and resources. *See id*. § 355(b).[6]

44. The FDCA provides a very narrow exemption to new drug approval requirements for drugs that are "compounded" by registered "outsourcing facilities." 21 U.S.C. § 353b.

45. Under the Section 503B exemption, an outsourcing facility that compounds using bulk drug substances is exempt from the FDCA's new drug approval requirements if (1) the drug compounded from "bulk drug substances" appears on the FDA's drug shortage list ("Drug Shortage List"), or (2) if the "bulk drug substances" appear on the FDA's list of bulk drug substances for which it has determined there is a "clinical need" ("Clinical Need List"). 21 U.S.C. § 353b(a)(2)(A)(i)-(ii).

46. An outsourcing facility cannot satisfy the 503B exemption simply by combining FDA-approved drugs or "bulk drug substances" that are included on either list, or at varying dosages, to sell an unapproved compounded drug. *Id.* § 353b(a)(2)(A)(i)-(ii).

47. In other words, a compounder cannot meet the 503B exemption just by combining drugs or bulk substances on the lists to create a new combined product that is not on these lists. *See id.*; 21 C.F.R. § 300.50.

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[6] Bright Focus Foundation, *FDA Approval Process* (Sept. 2, 2021), https://www.brightfocus.org/clinical-trials/how-clinical-trials-work/fda-approval-process; *Development & Approval Process*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/development-approval-process-drugs (last visited Nov. 1, 2023).

48. Because compounded drug products under the 503B exemption are not FDA-approved, they have not undergone FDA premarket review for safety and efficacy, and thus pose more "significant risks" to the American public.[7]

Pacira's EXPAREL® Product

49. When first introduced to the market in 2011, EXPAREL® created an entirely new category of post-operative pain management products, the Post-Surgical Non-Opioid Regional Analgesia Category.

50. Pacira's analgesic product – liposomal bupivacaine – was a new formulation of bupivacaine intended for single-dose infiltration at the surgical site for post-operative analgesia.

51. Through this novel formulation, bupivacaine is slowly released from this liposomal vehicle and can provide prolonged analgesia at the surgical site without the use of opioids.

52. Prior to EXPAREL®, the most common analgesic for treating moderate to severe post-operative pain were opioid products, which present significant and undesirable side effects for patients, including addictive qualities.[8]

53. Opioid-minimizing strategies can enhance recovery after surgery. Multimodal analgesia, featuring Pacira's EXPAREL® product, utilizes multiple pain management modalities for more effective pain control, which can lead to enhanced clinical and economic benefits.

54. EXPAREL® works locally at the surgical site and uses a proprietary technology to cause the bupivacaine to be released over time.

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[7] *FDA's Human Drug Compounding Progress Report*, U.S. Food & Drug Admin. 8 (Jan. 2017), https://www.fda.gov/files/drugs/published/Compounding-Safety-Report---2017.pdf.

[8] *See* Mana Saraghi, DMD, et al., *Three Newly Approved Analgesics: An Update*, Anesth. Prog. 178–87 (Winter 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3891458/pdf/i0003-3006-60-4-178.pdf (last visited Nov. 1, 2023).

55. Pacira's product has been clinically proven to significantly reduce pain during the crucial seventy-two (72) hours following surgery, decrease opioid use, delay the time until and/ or completely negate the patient's first opioid use following surgery, and improve patient satisfaction, as compared to other pain management products following a procedure.[9]

56. Pacira is the owner of U.S. trademark registration number 4,074,454, issued on December 20, 2011, for the mark EXPAREL® for "analgesics; preparation for the relief of pain; anesthetics for peri-operative and post-operative use; pharmaceutical preparations and substances for use in anesthesia and for the treatment and control of pain; liposome formulations containing preparations and substances for use in anesthesia and for the treatment and control of pain."[10]

57. Pacira promotes and advertises its EXPAREL® product, and the unique attributes of multimodal analgesia featuring Pacira's EXPAREL® product, through various channels, including on the website exparel.com and to physicians and licensed healthcare professionals, among others.

58. Pacira's efforts to educate the healthcare market on the benefits of the Post-Surgical Non-Opioid Regional Analgesia Category have been significant and sustained, including employing a field-based Clinical Education team, conducting and/ or sponsoring over 1,023 educational didactic workshops, cadaver labs, and Continuing Medical Education (CME) programs since 2018, sponsoring and authoring hundreds of peer-reviewed publications, and creating scores of procedure-dependent clinical practice guides and videos.

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[9] *See* Stephen R. Gorfine, et al., *Bupivacaine extended release liposome injection for prolonged postsurgical analgesia in patients undergoing hemorrhoidectomy: a multicenter, randomized, double-blind, placebo-controlled trial*, Dis Colon Rectum. 1552–59 (Dec. 2011), https://pubmed.ncbi.nlm.nih.gov/22067185/ (last visited Oct. 29, 2023).

[10] *See* EXPAREL, No. 4074454 (issued Dec. 20, 2011), *available at* https://uspto.report/TM/77464815 (last visited Nov. 1, 2023).

59. Pacira undertakes considerable efforts to build trust and confidence in the EXPAREL® brand and of multimodal analgesia featuring Pacira's EXPAREL® product.

60. Pacira also invests significant time, money, and effort to advertise and promote its EXPAREL® products, spending millions of dollars each year on such efforts.

61. Pacira's advertising for its EXPAREL® product, dating back over ten (10) years, includes core print 'leave-behinds,' a robust speaker program series, and a web and digital presence. Pacira has also invested millions of dollars in nationwide sponsorships, such as sponsorships with the Special Olympics and NFL Players Association, among many others.

62. As a result of Pacira's long use, promotion, and advertising of the EXPAREL® bupivacaine products, the EXPAREL® trademark is a well-known, strong and famous mark, and became famous prior to any of the acts of Defendant complained of herein.

63. The combination of the highest quality products and extensive promotional activities have kept the EXPAREL® brand at the forefront of the postsurgical pain management practice for caregivers throughout the United States for over a decade, and has resulted in millions of dollars of sales year after year.

Nephron's Acts

64. Nephron advertises and makes promotional claims about the BKK and RKK Unapproved Compounded Drug Cocktails which are literally false and/ or impliedly false and misleading because these Unapproved Compounded Drug Cocktails, which are not FDA-approved, are not generic to or substitutable for EXPAREL® (as they, *inter alia*, do not have technology causing the bupivacaine to be released over time, do not provide pain relief for up to 72 hours, and do not have any clinical testing supporting their use) and are not properly

advertised, offered for sale, or sold in competition with EXPAREL® in the Post-Surgical Non-Opioid Regional Analgesia Category (as they, *inter alia*, do not have any safety or efficacy data).

65. Upon information and belief, Nephron manufactures, advertises, offers for sale, and sells the BKK Unapproved Compounded Drug Cocktail as a multimodal analgesia injection to treat post-operative pain.

66. Nephron sells the BKK product in the Post-Surgical Non-Opioid Regional Analgesia Category in direct competition with EXPAREL®.

67. The BKK product consists of bupivacaine, ketorolac, and ketamine.

68. As Nephron has admitted, each component in the BKK Unapproved Compounded Drug Cocktail is administered and "used together as a preventive analgesic to manage post-surgical pain."[11]

69. Each of these components poses significant risks to patient safety and health if misused or administered in an unapproved manner.

70. Ketamine is a Schedule III controlled substance under the Controlled Substances Act ("CSA").[12] Its use may result in physical or psychological dependence and cause serious cardiovascular, respiratory, and psychological symptoms. *See* Schedules of Controlled Substances: Placement of Ketamine into Schedule III, 64 Fed. Reg. 37673 (July 13, 1999).

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[11] Nephron Pharmaceuticals Corporation, *Nephron Pharmaceuticals Corporation Releases Opioid Free Pain Management Product: BKK* (Dec. 13, 2018), https://www.nephronpharm.com/news/nephron-pharmaceuticals-corporation-releases-opioid-free-pain-management-product-bkk.

[12] U.S. Drug Enforcement Administration, *Controlled Substances: Alphabetical Order* 12, https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf (last visited Nov. 1, 2023).

71. Bupivacaine can lead to central nervous system and cardiovascular system reactions, while ketorolac may cause gastrointestinal ulceration, bleeding and perforation, renal failure, liver failure, and an increased risk of serious cardiovascular conditions.

72. Despite these known risks to patient health and safety, and even though this Unapproved Compounded Drug Cocktail has not been approved by the FDA or undergone any testing, Nephron nevertheless has aggressively marketed and sold the BKK product across the United States.

73. In this advertising, Nephron offers for sale and sells its BKK product as a replacement for, or equivalent to, Pacira's EXPAREL® bupivacaine product.

74. The BKK Unapproved Compounded Drug Cocktail does not have the proprietary multivesicular liposome (pMVL) technology found in the EXPAREL® product.

75. The BKK Unapproved Compounded Drug Cocktail does not provide pain relief for up to 72 hours.

76. Nephron claims that the BKK Unapproved Compounded Drug Cocktail does not require FDA approval because it meets the 503B exemption.

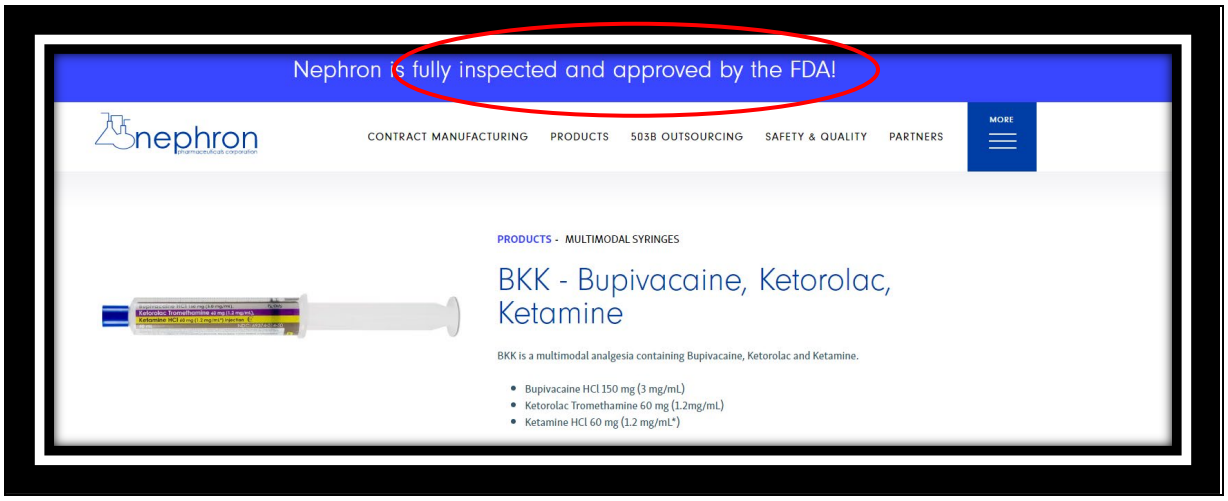
77. But BKK is not on the Drug Shortage List. While the list identifies each active ingredient of BKK on an individual basis, neither BKK nor any combination of bupivacaine, ketorolac, and ketamine appear on the list.

78. This Unapproved Compounded Drug Cocktail also consists of bupivacaine, ketorolac, and ketamine injections at concentrations not approved by the FDA or included on the Drug Shortage List.

79. Furthermore, neither the BKK Unapproved Compounded Drug Cocktail product nor its component bulk substances appear on the FDA's Clinical Need List.

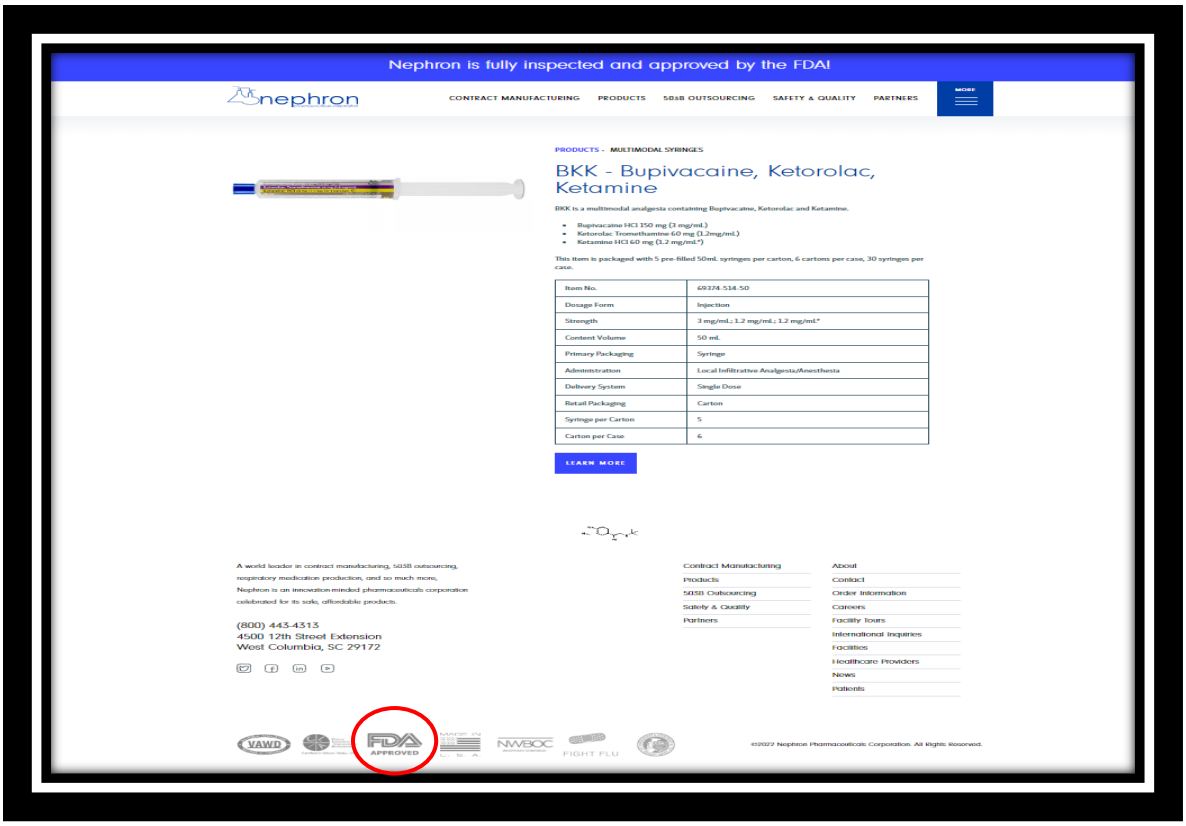
80. While Nephron claims to rely on the 503B exemption to sell BKK, its marketing and advertisements mislead the public to believe the FDA has approved this Unapproved Compounded Drug Cocktail.

81. For example, on webpage advertising for BKK, in immediate proximity to product information for this Unapproved Compounded Drug Cocktail, Nephron has made claims to "inspect[ion] and approv[al] by the FDA!" A copy of this page is set forth below:



82. That statement is false and misleading because it suggests that the FDA has reviewed and approved the BKK Unapproved Compounded Drug Cocktail, which it has not. Indeed, on information and belief, Nephron has not even requested the FDA to approve its Unapproved Compounded Drug Cocktail.

83. Additionally, when advertising the BKK Unapproved Compounded Drug Cocktail, Nephron on the product information page for BKK has featured a modified version of the logo mark of the FDA, doctored to state it is "FDA APPROVED," as set forth below:

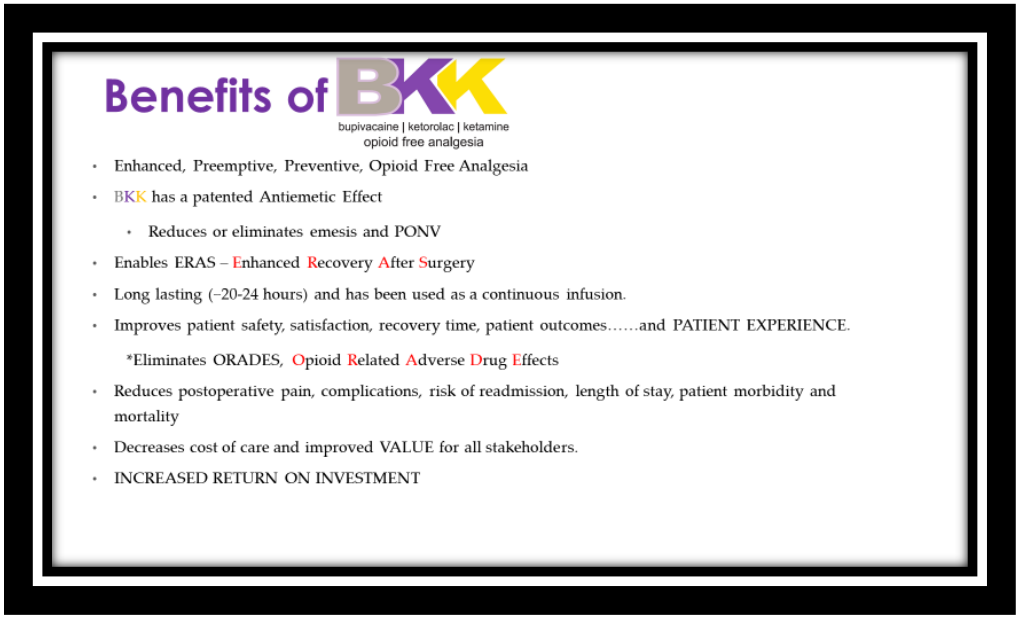


84. Again, that statement is false and misleading because it suggests that the FDA has reviewed and approved the BKK product, which it has not. Furthermore, the FDA logo is being falsely and improperly used to provide a further imprimatur of approval (and safety and efficacy) for this Unapproved Compounded Drug Cocktail.

85. Despite the fact that there is not a single study, let alone clinical trial, direct to this Unapproved Compounded Drug Cocktail, Nephron also makes advertising claims about BKK's efficacy and safety.

86. These claims and statements are false and misleading because they suggest that BKK has been shown to be safe and effective when it has not been.

87. In presentations made to hospitals and providers, Nephron has made unfounded claims about its efficacy as well as superiority over competitors, including EXPAREL®. An example of these presentations is provided below:



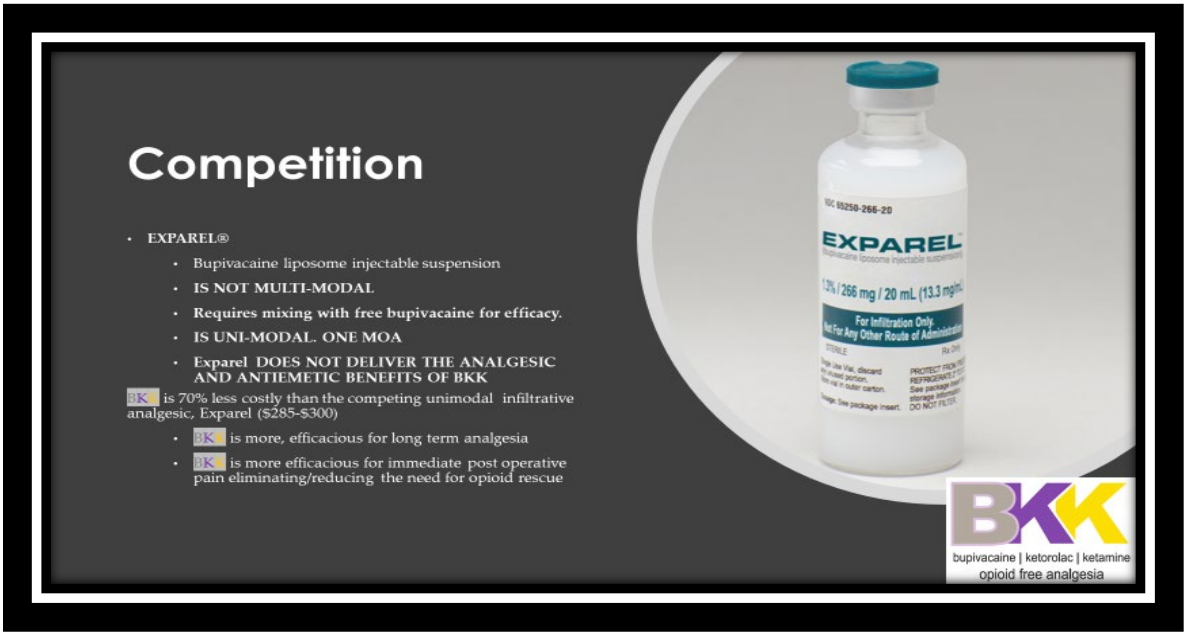
88. Nephron's claims that its Unapproved Compounded Drug Cocktail "improves patient safety, satisfaction, recovery time, patient outcomes" and improves "patient experience" are false and misleading: There are no clinical or other scientific trials or studies substantiating these claims.

89. Nephron's further claims that BKK "reduces postoperative pain, complications, risk of readmission, length of stay, patient morbidity and mortality" are false and misleading as Nephron does not have any support or clinical trials substantiating this claim.

90. Nephron has further specifically compared its product to EXPAREL®.

91. In doing so, Nephron makes additional unsupported claims about BKK's purported efficacy and safety.

92. For example, Nephron has advertised that BKK is more "efficacious for long term analgesia" and "post operative pain" than EXPAREL®, all without having any support or backing. The below excerpt from its advertising materials confirms as much:



93. Nephron provides no basis for this comparative superiority claim, and, upon information and belief, there is none.

94. None of Nephron's claims about BKK's efficacy and supposed benefits have been studied or validated by the FDA or other third-parties.

95. Nevertheless, Nephron has continued to make these brazen false and misleading advertisements and claims, as well as others, to market and sell BKK in interstate commerce throughout the United States.

96. In addition to BKK, Nephron, upon information and belief, manufactures, advertises, offers for sale, and sells the RKK Unapproved Compounded Drug Cocktail as a multimodal analgesic.

97. Nephron similarly sells the RKK product in the Post-Surgical Non-Opioid Regional Analgesia Category in direct competition with EXPAREL®.

98. The RKK product consists of ropivacaine (instead of bupivacaine), ketorolac, and ketamine.

99. Each of these component drugs pose significant risks to patient safety if administered in an unapproved manner or using improper dosages and concentrations.

100. Despite these known risks to patient health and safety, and even though this Unapproved Compounded Drug Cocktail has not been approved by the FDA or undergone any testing, Nephron nevertheless has aggressively marketed and sold the RKK product across the United States.

101. In this advertising, Nephron offers for sale and sells its RKK product as a replacement for, or equivalent to, Pacira's EXPAREL® bupivacaine product.

102. The RKK Unapproved Compounded Drug Cocktail does not have the proprietary multivesicular liposome (pMVL) technology found in the EXPAREL® product.

103. The RKK Unapproved Compounded Drug Cocktail does not provide pain relief for up to 72 hours.

104. Nephron claims that the RKK Unapproved Compounded Drug Cocktail does not require FDA approval because it meets the 503B exemption.

105. But RKK is not on the Drug Shortage List. While the list identifies each active ingredient of RKK on an individual basis, neither RKK nor any combination of ropivacaine, ketorolac, and ketamine appear on the list.

106. This Unapproved Compounded Drug Cocktail also consists of ropivacaine, ketorolac, and ketamine injections at concentrations not approved by the FDA or included on the Drug Shortage List.

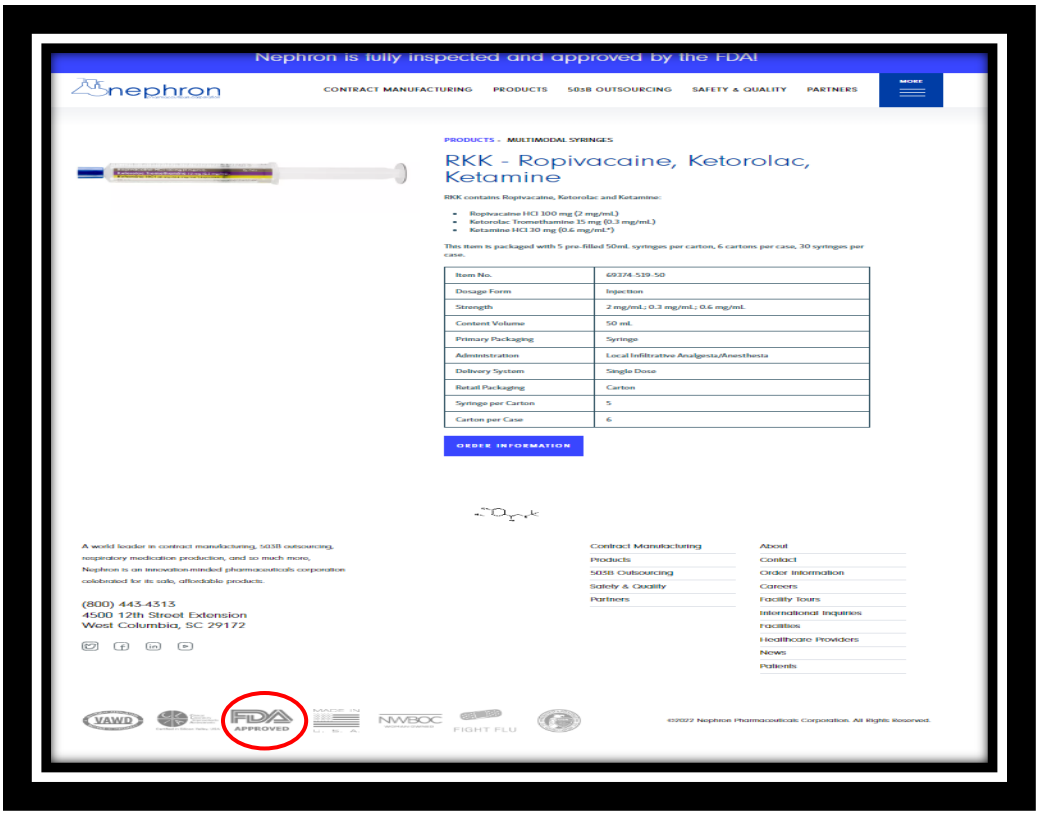
107. Furthermore, neither the RKK Unapproved Compounded Drug Cocktail product nor its component bulk substances appear on the FDA's Clinical Need List.

108. While Nephron claims to rely on the 503B exemption to sell RKK, its marketing and advertisements mislead the public to believe the FDA has approved this Unapproved Compounded Drug Cocktail.

109. For example, on webpage advertising for RKK, in immediate proximity to product information for this Unapproved Compounded Drug Cocktail, Nephron has made claims to "inspect[ion] and approv[al] by the FDA!" A copy of this page is set forth below:

110. That statement is false and misleading because it suggests that the FDA has reviewed and approved the RKK Unapproved Compounded Drug Cocktail, which it has not.

111. Additionally, when advertising the RKK Unapproved Compounded Drug Cocktail, Nephron on the product information page for RKK has featured a modified version of the logo mark of the FDA, doctored to provide a claim that the product is "FDA APPROVED," as set forth below:



112. Again, that statement is false and misleading because it suggests that the FDA has reviewed and approved the RKK product, which it has not. Furthermore, the FDA logo is being falsely and improperly used to provide a further imprimatur of approval (and safety and efficacy) for this Unapproved Compounded Drug Cocktail.

113. On information and belief, Nephron advertises, offers for sale, and sells BKK and/ or RKK, Unapproved Compounded Drug Cocktails, as comparable to, a generic of, substitutable for, or otherwise a replacement for FDA-approved EXPAREL®.

114. On information and belief, health care providers and consumers have reasonably relied on Nephron's false and misleading statements when deciding to purchase BKK or RKK instead of EXPAREL®.

115. In conjunction with its false and misleading statements and advertisements, Nephron intentionally sold BKK and RKK at prices well-below EXPAREL® to compete against Pacira and steal its market share by further inducing providers and hospitals to buy its drugs.

116. Because Nephron circumvented the FDA new drug approval process and attendant investment of time and capital, Nephron could price its Unapproved Compounded Drug Cocktails well below EXPAREL®.

117. On information and belief, Nephron has sold thousands of units of BKK and RKK to providers and hospitals in the United States.

118. By using its false and misleading statements and advertisements that both BKK and/ or RKK are generic to or substitutable for FDA-approved EXPAREL®, and that (notwithstanding the fact that there is absolutely no data whatsoever on the Unapproved Compounded Drug Cocktails, before the FDA or elsewhere) BKK was more "efficacious for long term analgesia" and "post operative pain" than EXPAREL®, among others, and also pricing BKK and RKK below the price of EXPAREL®, Nephron has engaged in false and misleading advertising to lure providers to purchase its unlawful drugs instead of EXPAREL®, to Pacira's detriment.

COUNT I
(False And Misleading Advertising And Promotion Under 15 U.S.C. § 1125(a)(1)(B))

119. Pacira realleges and incorporates by reference the allegations set forth in Paragraphs 1 through 118 of this Complaint as if fully set forth herein.

120. Nephron's practices, as described in this Complaint, constitute false and misleading advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

121. Nephron has violated the Lanham Act by using false and misleading advertising and marketing claims, or impliedly false advertising and marketing claims that misrepresent the nature, characteristics, and/ or qualities of Nephron's Unapproved Compounded Drug Cocktails sold in competition with EXPAREL®.

122. Nephron has made numerous false and/ or misleading statements on its website.

123. Among other false and misleading statements and advertisements, Nephron has claimed that:

- **BKK and RKK are generic to or substitutable for EXPAREL®**. This is literally false or impliedly false because these Unapproved Compounded Drug Cocktails, which are not FDA-approved, do not have technology causing the bupivacaine to be released over time, and do not provide pain relief for up to 72 hours.

- **BKK and RKK are FDA-approved.** That statement is false and misleading because the FDA has not approved either drug.

- **BKK "improves patient safety, satisfaction, recovery time, patient outcomes" and "patient experience."** These statements are false and misleading because Nephron has not conducted any clinical or other scientific trials.

- **BKK "reduces postoperative pain, complications, risk of readmission, length of stay, patient morbidity and mortality."** This claim is false and misleading because Nephron has not conducted any clinical or other scientific trials or studies.

- **BKK is more "efficacious for long term analgesia" and "post operative pain" than EXPAREL®**. These statements are false and misleading because Nephron has not conducted any clinical or other scientific trials or studies to support these assertions.

- **EXPAREL® "DOES NOT DELIVER THE ANALGESIC AND ANTIEMETIC BENEFITS OF BKK."** These statements are also false and misleading because Nephron has not conducted any clinical or other scientific trials or studies to support this assertion.

124. As a direct and proximate result of Nephron's knowing and willful false and misleading statements, false advertising, and wrongful acts of unfair competition, Pacira has

suffered injuries in fact and actual damages, including lost business, market share, sales, revenue, and profits.

125. By reason of the foregoing, Pacira is entitled to actual damages, treble damages, disgorgement of Defendant's profits, the costs of this action, and attorney's fees pursuant to 15 U.S.C. § 1117, as well as all other available remedies as set forth in its Prayer for Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Pacira BioSciences, Inc., prays for this Court to enter judgment against Nephron, granting the following relief:

1. Monetary relief, in the form of an award of Nephron's profits, for Nephron's false and misleading advertising and that this monetary relief be increased due to Nephron's willfulness pursuant to 15 U.S.C. § 1117 and as otherwise permitted by law;

2. Disgorgement of Nephron's profits by which Nephron has been unjustly enriched because of Nephron's unlawful actions;

3. Actual damages in an amount to be proven at trial pursuant to 15 U.S.C. § 1117 and as otherwise permitted by law;

4. Costs of suit herein pursuant to 15 U.S.C. § 1117 and as otherwise permitted by law;

5. Reasonable attorney's fees pursuant to 15 U.S.C. § 1117 and as otherwise permitted by law;

6. Pre-judgment, post-judgment, and other interest on all monetary damages, as permitted by law; and

7. Any and all such further relief that the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Pacira demands a trial by jury in this action on all issues so triable as of right.

Date: November 1, 2023

Respectfully submitted,

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